

AMENDMENTS TO THE CLAIMS

A complete list of claims as currently amended follows:

1. (currently amended) A pharmaceutical dosage form having a first and second active drug, said dosage form comprising:
 - (a) a controlled release core ~~comprising an antihyperglycemic drug~~ consisting essentially of metformin or a pharmaceutically acceptable salt thereof and at least one pharmaceutically acceptable excipient; and
 - (b) an immediate release thiazolidinedione derivative containing component wherein not less than 85%, of the thiazolidinedione is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0 , the thiazolidinedione derivative is pioglitazone or a pharmaceutically acceptable salt thereof and after storage at 40°C and 75% relative humidity for three months, the total thiazolidinedione related compounds or impurities in the dosage form is not more than 0.6% as determined by high performance liquid chromatography and each individual thiazolidinedione related compound or impurity in the final dosage form is not more than 0.25%.
2. (original) The pharmaceutical dosage form as defined in claim 1 wherein not less than 90%, of the thiazolidinedione is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.
3. (original) The pharmaceutical dosage form as defined in claim 1 wherein not less than 95%, of the thiazolidinedione is released from the dosage form within 45 minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.
4. (original) The pharmaceutical dosage form as defined in claim 1 wherein not less than 100%, of the thiazolidinedione is released from the dosage form within 45

minutes when tested according to the United States Pharmacopeia (USP) 26, with Apparatus 1 at 100 rpm, 37 °C and 900 ml of 0.3 M KCl-HCl Buffer, pH 2.0.

5. (canceled).
6. (canceled).
7. (canceled).
8. (canceled).
9. (canceled).
10. (canceled).
11. (canceled).
12. (canceled).
13. (canceled).
14. (canceled).
15. (currently amended) The pharmaceutical dosage form as defined in claim 1 ~~13~~ wherein the total thiazolidinedione related compounds are not more than 0.5%.
16. (canceled)
17. (currently amended) The pharmaceutical dosage form as defined in claim 15 ~~16~~ wherein each individual thiazolidinedione related compound or impurity in the final dosage form is not more than 0.20%.
18. (original) The pharmaceutical dosage form as defined in claim 17 wherein each individual thiazolidinedione related compound or impurity in the final dosage form is not more than 0.10%.
19. (original) The dosage form of claim 1 wherein said controlled release core is an osmotic tablet.
20. (currently amended) The dosage form of claim 19 wherein the osmotic tablet ~~comprises~~ consists essentially of:
 - (a) a core consisting essentially of ~~comprising~~:
 - (i) 50-98% of said metformin or pharmaceutically acceptable salt thereof ~~antihyperglycemic drug~~;
 - (ii) 0.1-40% of a binding agent;
 - (iii) 0-20% of an absorption enhancer; and

- (iv) 0-5% of a lubricant;
- (b) optionally a seal coat surrounding the core; and
- (c) a sustained release membrane comprising:
 - (i) 50-99% of a polymer;
 - (ii) 0-40% of a flux enhancer and
 - (iii) 0-25% of a plasticizer, said membrane having at least one passageway formed therein for release of the metformin or pharmaceutically acceptable salt thereof antihyperglycemic drug.
- 21. (canceled).
- 22. (canceled).
- 23. (original) The dosage form of claim 1 wherein said core is substantially free from any gelling or expanding polymer.
- 24. (currently amended) The dosage form of claim 1 wherein said controlled release of said metformin or pharmaceutically acceptable salt thereof antihyperglycemic drug provides a Tmax of 8-12 hours.
- 25. (original) The dosage form of claim 1 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-12 hours.
- 26. (original) The dosage form of claim 25 wherein said release of the thiazolidinedione derivative provides a Tmax of 1-4 hours.
- 27. (canceled).
- 28. (canceled).
- 29. (canceled).
- 30. (canceled).
- 31. (canceled).
- 32. (canceled).
- 33. (canceled).
- 34. (canceled).